CE

AVOXimeter® 4000

Whole Blood Oximeter

Operator's Manual

Manufacturing Company Location

International Technidyne Corp

8 Olsen Avenue, Edison, New Jersey USA

Phone: 1-732-548-5700

Fax: 1-732-248-1928

web site: www.itcmed.com

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U.S. Patents. 5,430,542 and 6,262,798. Euro/UK Patent 0663070. Other patents pending.

Technical Support

Contact ITC Technical Support at (800) 631-5945 or (732) 548-5700, or by e-mail at techsupport@itcmed.com.

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Important Labels and Symbols

Before using the ITC *AVOXimeter 4000*, it is essential that the contents of this *Operator's Manual*, any labels on the instrument or its packaging, and instructions accompanying ITC *AVOXimeter 4000* cuvettes are read and understood by the operator. These materials make reference to additional symbols that are explained below:

CE	Product Conforms to Directive 98/79, 27 October 1998 on In-Vitro Diagnostic Medical Devices
SN	Serial Number of Instrument
LOT	Lot Number of Cuvettes
REF	ITC Catalogue Number of Devices
2	Do Not Reuse– Single Use Only
	Upper and Lower Temperature Limitations (For Storage or Use)
IVD	For *in vitro* Diagnostic Use
	Attention - Read Accompanying Documentation or Instructions
	Consult Instructions for Use
+ — ⊖ — - 12.0VDC⎓/800mA	Input Port for DC Power Cord from AC/DC Power Module - Polarity, VDC and A Input
|O|O|	Serial Output Port for Data Transfer – RS232C
	Temperature Probe Input
	Name and Address of Manufacturer
	Warning - Biohazard
	Medical Equipment per Annex 1A, Item 8 Directive 2002/96/EC For Electronic Equipment Waste – Contact ITC Technical Support @ 1-800-631-5945

1 Introduction

Intended Use of the ITC *AVOXimeter 4000*

The ITC *AVOXimeter 4000* is a battery-operated desktop whole blood oximeter that performs individual point-of-care measurements of total hemoglobin (tHb), oxyhemoglobin saturation (%0_2Hb), carboxyhemoglobin (%COHb), and methemoglobin (%MetHb) on freshly-drawn or heparin- or EDTA-anticoagulated whole blood samples. Oxygen content ([0_2Ct]), percent saturation (SO_2) and oxygen carrying capacity (O_2Cap) of the blood sample are automatically calculated from the %Hb0_2 and THb measurements.

No sample preparation is required, and analysis is quickly accomplished by injecting the sample into a disposable cuvette and inserting the cuvette into the instrument. The ITC *AVOXimeter 4000* then illuminates the sample with multiple wavelengths, records the optical density of the sample at each of the wavelengths, and computes the results. In less than 10 seconds, the total hemoglobin concentration and the percentages of oxyhemoglobin, carboxyhemoglobin, and methemoglobin in the sample are shown in appropriate units on the liquid-crystal display on the front panel.

Data management capabilities are included with the instrument. These capabilities include storage of up to 100 patient or QC results, designation of quality control levels and lot numbers, tagging of test results with date, time, Patient ID and/or Operator ID, and printing of results.

IVD

Summary and Explanation of the Test

The ITC *AVOXimeter 4000* measures whole blood tHb, %02Hb, %COHb, and %MetHb using disposable single-use cuvettes. The operator inserts a whole blood sample into a cuvette, the cuvette is inserted into the test chamber on the instrument, and the results are displayed. The results will remain on the display after the cuvette is removed from the instrument until any key is pressed, clearing the screen.

The result can be automatically printed along with the time and date the test was run, the Patient ID, Operator ID, and other information entered. The result is also saved in an internal database, which has the capability to store up to 100 results.

Up to three liquid control lot numbers for each level of Liquid Quality Control (LQC) can be stored in the *ITC AVOXimeter 4000* and must be tagged to the stored or printed records. Cuvette lot numbers can also be tagged to the LQC records. The instruments can be configured so that only authorized operators can operate the system and that patient IDs can be entered for each test run.

The ITC *AVOXimeter 4000* measures oxygenated hemoglobin (O_2Hb), reduced hemoglobin (HHb), methemoglobin (MetHb), and carboxyhemoglobin (COHb) directly, using novel optics and multiple wavelengths. This reduces interference from dyshemoglobins and other interfering substances such as fetal hemoglobin and bilirubin and minimizes the effects of hemolysis.

The measured values are used to calculate total hemoglobin (tHb) and percent oxyhemoglobin saturation [%02Hb] of the sample, using the fractional method described below:

$$(tHb) = (O_2Hb) + (HHb) + (MetHb) + (COHb)$$

$$\%O_2Hb = \frac{(O_2Hb) \times 100}{(tHb)}$$

Oxygen content [O_2Ct] of the sample is then calculated:

$$O_2Ct = \frac{1.39 \times tHb \times \% O_2Hb}{100}$$

where 1.39 is the amount of oxygen assumed to be carried by one gram of oxygenated hemoglobin (Hüfner's Number). Depending on your facility protocols, the Hüfner's Number stored in the ITC *AVOXimeter 4000* can be set at any value in the range of 1.30 to 1.39 (see page 28).

Glossary of Abbreviation Equivalents

In some cases, the display screen of the *ITC AVOXimeter 4000* does not show the most commonly used format for a specific constituent's abbreviation. Below is a glossary of abbreviation equivalents to ensure that users fully understand each reading on the *ITC AVOXimeter 4000* display.

Constituent	AVOXimeter 4000 Display	Conventional Equivalent
Total Hemoglobin	tHb	tHb
Fractional O_2 Saturation	sO_2	SO_2
Oxygen Content	O2Ct	O_2CT
Carboxyhemoglobin	COHb	COHb
Methemoglobin	MetHb	MetHb
Oxyhemoglobin Saturation	$\%O_2Hb$	$\%O_2Hb$

Operating Precautions and Warnings

- For *in vitro* Diagnostic use.
- Do not allow blood, water, or other liquids to enter the instrument.
- The ITC *AVOXimeter 4000* instrument is designed for use only with *ITC AVOXimeter 4000* cuvettes.
- Do not re-use test cuvettes.
- Always keep cuvettes in sealed bag with desiccant, and replace desiccant if the indicator dot on the desiccant pack indicates the presence of mositure.
- When filling cuvette, do not use excessive pressure on the syringe or cause the vent patch to bulge outward by overfilling the cuvette.
- For proper calibration and calibration verification, use only the controls recommended in this manual. Controls from other sources may yield erroneous results.
- The ITC *AVOXimeter 4000* instrument is designed to be used for testing in a stationary position. DO NOT perform testing while carrying or holding the instrument.
- In order to charge the ITC *AVOXimeter 4000* instrument, the AC power cord should be plugged into an electrical service outlet and the AC/DC power module while the DC power cord from the AC/DC power module is plugged into the DC port in the back of the instrument.
- DO NOT expose the ITC *AVOXimeter 4000* instrument to extreme temperature (above 35°C, 95°F). Such exposure could affect the performance of any type of electronic instrumentation.
- DO NOT drop the ITC *AVOXimeter 4000* instrument, and do not use the results if the instrument is dropped during a test.
- Only properly qualified personnel should attempt to open and perform work on the ITC *AVOXimeter 4000* instrument as identified in this manual.
- DO NOT remove the AC/DC power module from the ITC *AVOXimeter 4000* instrument by pulling on the cord.
- The use of accessory equipment (e.g., printers, etc.) not identified in this manual either in the patient vicinity, or that does not comply with either the equivalent safety requirements of this equipment or UL/IEC 60601-1 or IEC 60601-1-2, may lead to a reduced level of safety with the resulting system.

Any items exposed to human blood, plasma or serum must be handled cautiously as a biohazardous material in accordance with laboratory safety practices and federal and local regulations. Federal, state and local laws and regulations require that hazardous waste be disposed of in a specific manner. Waste material from the ITC *AVOXimeter 4000* which may be classified as biohazardous include used cuvettes. It is important that steps be taken to dispose of these materials in accordance with the prevailing regulations in your location.

Limitations

Do not disturb the instrument while a test is in progress.

As with all diagnostic tests, ITC *AVOXimeter 4000* test results should be scrutinized in light of a specific patient's condition and therapy. Any results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional test data.

2 Description

The ITC *AVOXimeter 4000* (Figure 1) is a tabletop device for use at the bedside. It contains a test chamber which performs all operations to measure the concentrations of reduced oxyhemoglobin (HHb), oxyhemoglobin saturation (%0_2Hb), carboxyhemoglobin (COHb), and methemoglobin (MetHb) of a whole blood sample after the operator inserts a test cuvette containing the sample into the test chamber.

The concentration of total hemoglobin (tHb), the relative fractions of carboxyhemoglobin (%COHb) and methemoglobin (%MetHb), and the oxygen content (0_2) of the blood sample are then automatically calculated and reported.

Each ITC *AVOXimeter 4000* is calibrated at the factory. The ITC *AVOXimeter 4000* can be operated either from its internal batteries or from the AC adapter. The batteries are charged whenever the AC Adapter is connected.

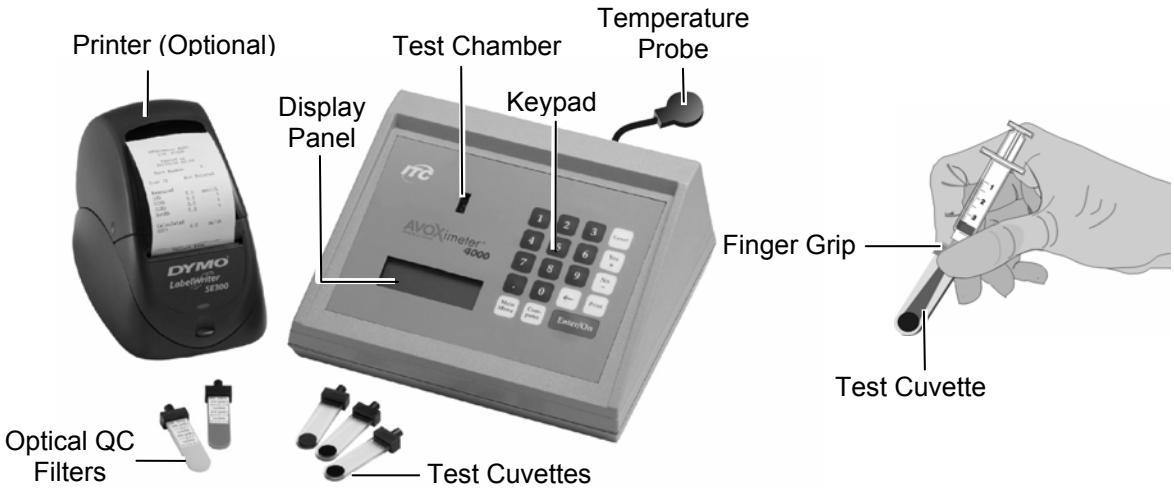

Figure 1. ITC *AVOXimeter 4000* Oximeter

Front Panel

The front panel (Figure 2) contains the test chamber, a keypad with the Enter/On key, action and menu keys, number keys, and a display panel. Operator instructions are shown on the display panel, and the operator enters commands and information using the keypad.

When the test is completed, the results are shown on the display panel and stored in system memory for current or future printing.

The display panel is illuminated to enhance visibility in low light conditions. The illumination can be adjusted (or turned off) to conserve power during battery operation.

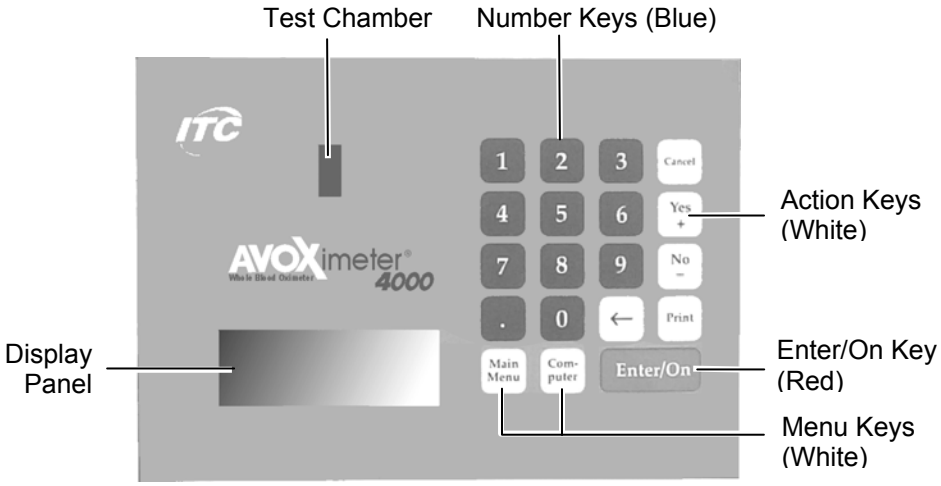

Figure 2. Front Panel

Keypad

The routine analysis of blood samples does not require the use of menus or the numeric keypad. However, these enable the user to take advantage of many useful features.

The purpose of each key is summarized below:

Key	Purpose
Enter/On	Switch the instrument on. Select a command.
Main Menu	Display a menu of commands for calibration, printing, stored data, and shutdown.
Com-puter	Display a menu of commands for entering hemodynamic variables, entering device settings, entering the time and date, viewing battery status and temperature, and managing data.
Print	Print the results that are displayed.
Yes + and No --	Respond to questions that are displayed.
←	Backspace over a numerical entry (such as a QC lot number) so that it can be corrected.
Cancel	Return to the previous menu.
1 to 0	Enter characters for Operator IDs or Patient IDs. Enter a character for selection of a command.

Menus

The principal menus, their commands, and the procedure to access each menu are summarized below:

Note: *Press the Cancel button at any time to return to the previous menu.*

Menu	Commands	Access
Main Menu	1. Calibration 2. Printer Mode 3. Stored Data 4. Turn Off	Press the Main Menu key when a test is not running or another menu is not active.
Calibration Submenu	1.Cuvette Cal Code 2.Cuvette Lot Number 3.Hüfner's# 1.30-1.39	Press 1 followed by Enter/On while the main menu is displayed.
Printer Mode Submenu	1.Auto Print ON/OFF 2.Print Stored Data 3.Printer Parameters	Press 2 followed by Enter/On while the main menu is displayed.
Stored Data Submenu	1. Select SamPle # 2. Newest SamPle 3. Transfer Data Use +/- to Scroll	Press 3 followed by Enter/On while the main menu is displayed.
Computer Menu	1. Data Management 2. Device Settings 3. Time, Date, TemP	Press the Com-puter key when a test is not running or another menu is not active.
Data Management Submenu	1.DataTransferON/OFF 2.User ID ON/OFF 3.Patient ID ON/OFF 4.QC Lot	Press 1 followed by Enter/On while the computer menu is displayed.
Device Settings Submenu (Page 1)	1. LCD 2. Units 3. Standby Delay 4. More Settings	Press 2 followed by Enter/On while the computer menu is displayed.
Device Settings Submenu (Page 2)	1. Oxygen Sat. (sO2) 2. Neg. SuPPression	Press 4 followed by Enter/On while Page 1 of the device settings menu is displayed.
Time, Date, and Temperature Submenu	1. Set & View Time 2. Set & View Date 3. TemP & Battery	Press 3 followed by Enter/On while the computer menu is displayed.

Test Cuvettes

Tests are performed with single-use disposable test cuvettes (Figure 3). Each test cuvette contains a finger grip, filling port, optical window, and a vent patch.

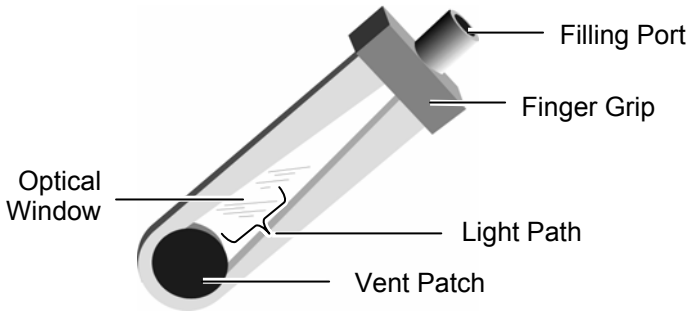

Figure 3. Test Cuvette

A whole blood sample is inserted into a test cuvette by connecting a small syringe containing the whole blood sample to the filling port and then gently pressing the syringe plunger to dispense approximately 50 µL of whole blood into the test cuvette. Air escapes from the vent patch at the end of the test cuvette while the whole blood sample is being inserted. The test cuvette (with the syringe still attached) is then inserted into the test chamber of the instrument (see page 32 for details).

Note: *Be sure to handle the cuvette either by the edges or by the finger grip. Refer to the package insert accompanying the test cuvettes for storage and handling instructions.*

- **Remove any blood or debris from the exterior of the test cuvette before inserting it into the test chamber.**
- After filling the cuvette with blood, inspect the vent patches to ensure they are not bulging out. If a vent patch protrudes, discard the cuvette. **Do not insert a cuvette with a protruding vent patch into the test chamber**.

BIOHAZARD WARNING: Any items exposed to human blood, plasma or serum must be handled cautiously as a biohazardous material in accordance with laboratory safety practices and federal and local regulations. Federal, state and local laws and regulations require that hazardous waste be disposed of in a specific manner. Waste material from the ITC *AVOXimeter 4000* which may be classified as biohazardous include used cuvettes. It is important that steps be taken to dispose of these materials in accordance with the prevailing regulations in your location.

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Connections

Connections to the power supply and an optional printer (or a computer) are made at the rear of the instrument (Figure 4).

Use only the power supply provided with the instrument.

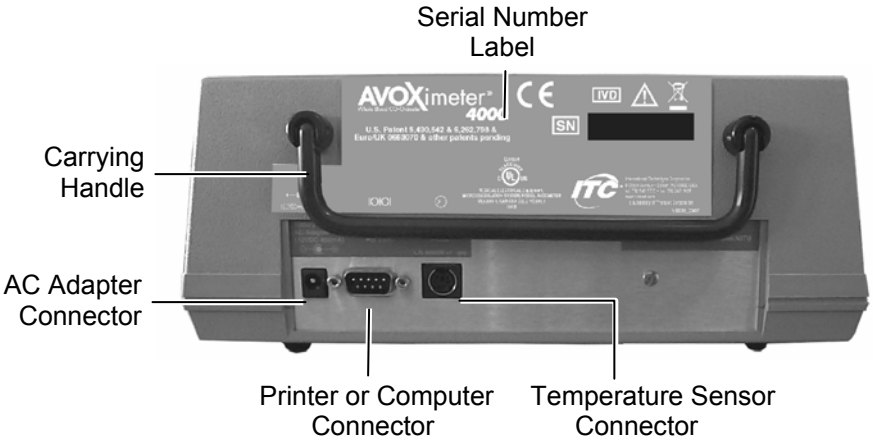


Figure 4. Rear Panel Components

Automatic Standby and Shutdown

The ITC *AVOXimeter 4000* enters a low-power standby mode after the instrument has been idle for a specified period of time (the **standby delay**). The instrument is factory preset for a standby delay time of 60 minutes, but a time of **10** to **180** minutes can be specified (see page 18). To resume normal operation when the instrument is in standby, press and hold down any key for one second.

Note: *The ITC AVOXimeter 4000 also enters standby if the battery charge becomes critically low.*

The ITC *AVOXimeter 4000* shuts down after it has been in standby for 4 hours.

Instrument Lockouts

The instrument can be configured to allow use only by authorized operators and/or to allow use only if optical QC has been performed.

Instrument Specifications

Size	20.3 cm (8.0 in) x 25.4 cm (10.0 in) x 9.5 cm (3.8 in)
Weight	1.8 kg (4 lbs)
Operating Temperature	Room temperature (15°C to 30°C, 59°F to 86°F)
Battery Type	Nickel Cadmium (NiCad)
Operating Time On Battery	Approximately 8 hours (constant run) or 10 complete test cycles per charge. Tests may also be run while the ITC *AVOXimeter 4000* is plugged into the AC/DC power module.
Anticipated Battery Life	Approximately 500 charge / discharge cycles
Power Supply/Chargers	Input: 100 / 240 VAC, 50 / 60 Hz Output: 12 VDC, 800 mA
Serial Data Port	RS232C
Sample Type	Whole blood
Sample Volume	50 µL
Analysis Time	7 to 10 seconds per sample
Analysis Wavelengths	5

Reportable Range

tHb	4 to 25 g/dL
%O_2Hb	0 to 100%
%COHb	0 to 75%
%MetHb	0 to 85%
[O_2]	0 to 35 mL O_2/dL

Accuracy

tHb (>10 g/dL)	±0.45 g/dL
tHb (<10 g/dL)	±0.35 g/dL
%O_2Hb	±1.6%
%COHb	±2%
%MetHb	±1.5%

Precision

tHb	0.3 g/dL
%O_2Hb	0.8 % O_2Hb
%COHb	1 % COHb
%MetHb	0.7 % MetHb

Interferences

	tHb	$\%O_2Hb$	%COHb	%MetHb
Bilirubin (11 mg/dL)	None	None	< 1%	< 1%
Hemolysis	None	None	< 1%	< 1%
Fetal Hemoglobin (tHb = 13.5 g/dL, HbF = 100%	< 0.45 g/dL	< 1%	< 0.6% per %HbF	< 1%
Indocyanine Green Dye (<10 mg/L)	< 0.45 g/dL	< 1%	< 1%	< 1%
Methemoglobin (tHb = 16 g/dL, MetHb <10%, 7.1 < pH < 7.8)	< 0.2 g/dL	< 1%		

Calibration

The *ITC AVOXimeter 4000* is factory-calibrated and employs highly stable state-of-the-art light sources. Should recalibration be required please contact an ITC technical support representative.

Proper calibration also requires entry of the correct cuvette pathlength by the user (see page 26) and use of a customary value for Hüfner's number (see page 26).

***CAUTION**: If quality control results are not acceptable, erroneous results are encountered, or error messages are displayed, the most likely cause may be contamination of the optical detector by blood or debris, which cannot be resolved by re-calibration. Consult the Troubleshooting section for additional information.*

3 Getting Started

Unpacking and Inspection

Note: *Inspect each component for damage when unpacking. If damage is observed, contact your shipping representative immediately.*

1. Remove any protective packaging that may be present around the instrument.
2. Examine the packaging material to be sure that the AC Adapter, temperature probe, connecting cables, or other components have been removed. The materials that are provided are listed below.

   Note: *Do not discard the packaging material. It should be preserved for future use, in the event that it is necessary to re-pack the instrument for shipping or transport.*

Materials Provided

Item	Quantity
ITC AVOXimeter 4000 Instrument	1
Power Supply	1
Temperature Probe	1
Operator's Manual	1
Quality Control Filters	2

Note: *An AC power cord is supplied only for the 110VAC version of the US/Canada/Japan instrument. For all others, the customer must obtain a 3 conductor AC power cord that is compatible with an IEC 320 connection at the power supply AC inlet and any other local requirements.*

Materials Required But Not Provided

Item	Quantity
ITC AVOXimeter 4000 Cuvettes	As Needed
Liquid Controls (Manufactured by IL or RNA) See page 39 for additional information	As Needed

Optional Materials

Item	Quantity
Dymo Printer • 110 V (Part No. SE300-110) • 220 V (Part No. SE300-220) • UK (Part No. SE300-UK)	1
Printer Paper (Part No. 30270)	As Needed

Charging the Batteries

Charge the batteries before the system is used for the first time.

1. Plug the AC Adapter into an electrical service outlet.
2. Connect the AC Adapter cord to the power connector on the rear of the instrument.
3. Allow the battery to charge for at least eight hours.

   Note: *The AC Adapter can remain connected all the time.*

4. To ensure adequate charge, leave the instrument connected to the AC Adapter for a minimum of eight hours. This eliminates the risk of the instrument powering down during a test.

Fully charged batteries will allow the ITC *AVOXimeter 4000* to analyze blood samples continuously for up to 8 hours when the display is set at medium brightness.

Battery power can be conserved by:

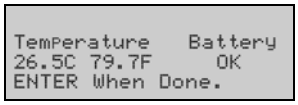
- Reducing (or turning off) display backlighting (see page 15).
- Reducing the standby delay (see page 18).

Note: *The batteries can suffer from a "memory effect" if they are charged before being completely discharged. For optimal battery performance, discharge completely when possible before charging them. The message "**Battery Critical – Connect Charger"** will be displayed when the battery is completely discharged.*

The message "**Battery Critical – Connect Charger**" is displayed and the instrument reverts to the standby mode if the battery power is insufficient to complete the test. The AC Adapter must be used for additional tests until the battery is recharged.

Checking the Battery:

1. Display the "Time, Date, and Temperature" menu (a submenu of Com-puter, see page 7).
2. Press 3 followed by Enter/On to display the battery status:



3. Press Enter/On to display the time, date, and battery menu again.

4. Press Cancel to return to the previous menu, if desired.

Setting Up the Instrument

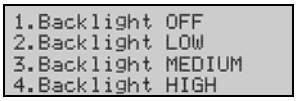
The user can specify the display brightness, specify the units that are used for reporting total hemoglobin (THb), change the date and time, and specify the length of time that the instrument is idle before it enters the standby mode.

Setting Display Backlighting

Lighting of the display can be reduced to conserve battery power or increased to improve visibility.

1. Display the "Device Settings" menu (a submenu of Com-puter, see page 7).

2. Press 1 followed by Enter/On to display the screen for changing the LCD backlighting:



3. Select the backlighting level (or turn it off) by pressing the corresponding number key followed by Enter/On. The backlighting changes accordingly.

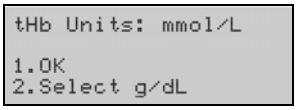
4. Press Cancel to display the "Device Settings" menu again.

Specifying Units for Total Hemoglobin (THb)

Measured values of total hemoglobin can be expressed in units of mmol/L or gm/dL.

1. Display the "Device Settings" menu (a submenu of Com-puter, see page 7).

2. Press 2 followed by Enter/On to display the screen for changing the units for total hemoglobin:



3. Press 2 followed by Enter/On to change the units, or press 1 followed by Enter/On when the desired units are displayed. The "Device Settings" menu is again displayed.

4. Press Cancel to return to the previous menu, if desired.

Enabling or Disabling Display of SO_2, O_2Ct, and O_2Cap

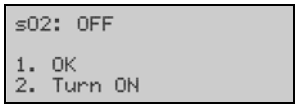
Display of calculated oxygen content (0_2Ct), percent saturation (SO_2) and oxygen carrying capacity (O2Cap) of the blood sample can be enabled or disabled.

Note: *Oxygen content (0_2Ct), percent saturation (sO2), and oxygen carrying capacity (O_2Cap) are automatically calculated for each test.*

When display of these values is enabled, these values are displayed on the second page (of three pages) when results are reviewed in the 'stored data' menu (see page 36), and they are included in printed test results.

Only measured values of tHb, $\%HbO_2$, %COHb, and %MetHb are displayed on the instrument display panel after a test is run, regardless of whether display of calculated oxygen content (0_2Ct), percent saturation (SO_2), and oxygen carrying capacity (O2Cap) of the blood sample is enabled.

1. Display the second page of the "Device Settings" menu (a submenu of Com-puter).
2. Press 1 followed by Enter/On to display the screen for enabling or disabling display of calculated (0_2Ct), (SO_2), and (O_2Cap) for each test:



3. Select the appropriate option by pressing the corresponding number key followed by Enter/On. A corresponding confirmation prompt is displayed.
4. Press Cancel to return to the previous menu, if desired.

Enabling or Disabling Suppression of Negative Values

Users can choose to display or suppress negative values.

Note: *Negative values may occur because in some cases, due to instrument precision ranges, a very low Met- or Carboxyhemoglobin value may read as a negative value. Users can choose to suppress negative values, and have them read as '0'.*

1. Display the second page of the "Device Settings" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the screen for enabling or disabling display of negative values:

3. Select the appropriate option by pressing the corresponding number key followed by Enter/On. A corresponding confirmation prompt is displayed. Press Cancel to return to the previous menu, if desired.

Changing the Date and Time

Changing the Time:

1. Display the "Time, Date, and Temperature" menu (a submenu of Com-puter, see page 7).
2. Press 1 followed by Enter/On to display the current time:

```
     (HHMM)
Time: 0911    (24 hr)
1. OK
2. Enter New Value
```

3. Press 2 followed by Enter/On to change the time:

```
     (HHMM)
Time: ■       (24 hr)
```

4. Use the number keys to enter the new time, then press Enter/On. The new time is displayed.

```
     (HHMM)
Time: 0811    (24 hr)
1. OK
2. Enter New Value
```

Note: *The time is displayed in 24-hour format. For example, 3:30 pm is displayed as **1530**.*

5. Press 1 followed by Enter/On. The "Time, Date, and Battery" menu is again displayed.
6. Press Cancel to return to the previous menu, if desired.

Changing the Date:

1. Display the "Time, Date, and Battery" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current date:

```
     (MMDDYY)
Date: 012107
1. OK
2. Enter New Value
```

3. Press 2 followed by Enter/On to change the date:

```
     (MMDDYY)
Date: ■
```

4. Use the number keys to enter the new date, then press Enter/On. The new date is displayed.

```
     (MMDDYY)
Date: 012207
1. OK
2. Enter New Value
```

5. Press 1 followed by Enter/On. The "Time, Date, and Battery" menu is again displayed.

6. Press Cancel to return to the previous menu, if desired.

Setting the Standby Delay

The instrument enters a low-power Standby mode after being inactive for a specified length of time (the Standby Delay). The instrument is factory preset for a standby delay time of 60 minutes, but a time of **10** to **180** minutes can be specified.

1. Display the "Device Settings" menu (a submenu of Com-puter, see page 7).

2. Press 3 followed by Enter/On to display the standby delay (**60** minutes is the factory default value):

```
Standby Delay in
Minutes: **** 60****
1.OK
2.Enter New Value
```

3. Press 2 followed by Enter/On to display the screen for changing the standby delay:

```
Set Standby Delay in
Minutes: _       ****
Range:10-180 minutes
0 Disables Delay
```

4. Use the number keys to enter the new standby delay (or disable the standby delay), then press Enter/On. The new standby delay is displayed.

```
Standby Delay in
Minutes: **** 30****
1.OK
2.Enter New Value
```

5. Press 1 followed by Enter/On. The "Device Settings" menu is again displayed.

6. Press Cancel to return to the previous menu, if desired.

Specifying Entry of User ID and/or Patient ID

A User ID and/or Patient ID can be entered for any test. The User ID and/or Patient ID is included in the results record for tests that are run and can be included in the printed results. Three alternatives are available for entry of User ID:

- Authorized User ID with Security: Entry of an authorized User ID from a list of authorized users is required in order to start the instrument and is not again prompted for until the instrument is restarted. The User ID that is entered to operate the instrument is included on all test records and can also be included on printed test results if specified.
- Authorized User ID without Security: Entry of a numeric User ID is prompted for whenever a test is run. The operator can enter any numeric User ID (up to nine digits, with no leading zeros) or the operator can bypass entering a User ID for that test. If a User ID is entered, that User ID is included on the test record and can be printed with test results.
- Authorized User ID Disabled: A User ID cannot be entered.

A prompt can also be enabled for optional entry of a Patient ID whenever a test is run.

Specifying Mandatory Entry of an Authorized User ID

Enabling the Requirement to Enter an Authorized User ID:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current User ID setting:

```
User ID: OFF

1. OK
2. Turn ON
```

3. Press 2 followed by Enter/On. A confirmation prompt is displayed, and the "Security" menu is displayed:

```
Security:  OFF

1. OK
2. Turn ON
```

4. Press 2 followed by Enter/On. A confirmation prompt is displayed, and the "Authorized User ID" menu is displayed:

```
1. Review/Delete
2. Add User
3. Print User List
4. Print ID ON/OFF
```

Note: *The authorized User ID must be re-entered if the instrument is idle for longer than 15 minutes or is turned off.*

5. If needed, review the list of authorized users, add or delete authorized users, print the authorized user list, and/or specify whether authorized User IDs are included in the results printout (see below).

6. Press Cancel to display the "Data Management" menu.

Disabling the Requirement to Enter an Authorized User ID:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current User ID setting:

```
User ID: ON

1. OK
2. Turn OFF
```

3. Press 2 followed by Enter/On. A confirmation prompt is displayed, and the "User and Patient ID" menu is again displayed.
4. Press Cancel to return to the previous menu, if desired.

Adding an Authorized User ID:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current User ID setting:

```
User ID: ON

1. OK
2. Turn OFF
```

Note: ***User ID****: must be* ***ON*** *to proceed.*

3. Press 1 followed by Enter/On. The "Security" menu is displayed:

```
Security:  ON

1. OK
2. Turn OFF
```

Note: ***Security****: must be* ***ON*** *to proceed.*

4. Press 1 followed by Enter/On to display the "Authorized User ID" menu:

```
1. Review/Delete
2. Add User
3. Print User List
4. Print ID ON/OFF
```

5. Press 2 followed by Enter/On to display the screen for entering a new User ID:

```
   Enter User ID:
*****         ******
 (Up to  9 digits;
  no leading zeros)
```

6. Enter the new User ID, using the number keys, then press Enter/On. A confirmation screen is displayed.
7. Press 1 followed by Enter/On to confirm the new User ID. The "User ID" menu is again displayed.

8. Press Cancel to return to the previous menu, if desired.

Reviewing and/or Deleting Authorized User IDs:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current User ID setting:

```
User ID: ON

1. OK
2. Turn OFF
```

   Note: ***User ID****: must be* ***ON*** *to proceed.*

3. Press 1 followed by Enter/On. The "Security" menu is displayed:

```
Security:  ON

1. OK
2. Turn OFF
```

   Note: ***Security****: must be* ***ON*** *to proceed.*

4. Press 1 followed by Enter/On to display the "Authorized User ID" menu:

```
1. Review/Delete
2. Add User
3. Print User List
4. Print ID ON/OFF
```

5. Press 1 followed by Enter/On to display the first User ID in the list:

```
User ID:      4733
+/- to Scroll
1.Return to PrevMenu
2.Delete This ID
```

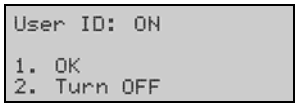
6. Press Yes + or No - to scroll through the list of users. To delete a user, display that user, press 2 followed by Enter/On, and respond Yes + to the confirmation prompt.

   Note: *The default QA User ID is* ***123456****. The default QA User ID cannot be deleted.*

7. Press 1 followed by Enter/On to display the "Authorized User ID" menu.
8. Press Cancel to return to the previous menu, if desired.

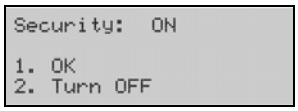
Printing a List of Authorized User IDs:

1. Prepare the printer (see page 35).
2. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
3. Press 2 followed by Enter/On to display the current User ID setting:



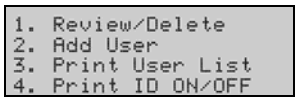
Note: ***User ID****: must be* ***ON*** *to proceed.*

4. Press 1 followed by Enter/On. The "Security" menu is displayed:

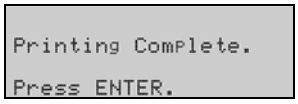


Note: ***Security****: must be* ***ON*** *to proceed.*

5. Press 1 followed by Enter/On to display the "Authorized User ID" menu:



6. Press 3 followed by Enter/On to print the list. A message is displayed after the list has printed:



7. Press Enter/On to display the "User ID" menu.
8. Press Cancel to return to the previous menu, if desired.

Specifying Whether Authorized User IDs are Included on Results Printouts:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current User ID setting:

```
User ID: ON

1. OK
2. Turn OFF
```

Note: ***User ID****: must be* ***ON*** *to proceed.*

3. Press 1 followed by Enter/On. The "Security" menu is displayed:

```
Security:  ON

1. OK
2. Turn OFF
```

Note: ***Security****: must be* ***ON*** *to proceed.*

4. Press 1 followed by Enter/On to display the "Authorized User ID" menu:

```
1. Review/Delete
2. Add User
3. Print User List
4. Print ID ON/OFF
```

5. Press 4 followed by Enter/On to display the "User ID on Printout" menu:

```
User ID on
Printout: OFF
1. OK
2. Turn ON
```

6. Press 2 followed by Enter/On to change the setting. A confirmation prompt is displayed, and the "Authorized User ID" menu is displayed.
7. Press Cancel to return to the previous menu, if desired.

Specifying Optional Entry of a User ID Whenever a Test is Run

Enabling Optional Entry of User IDs:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current User ID setting:

```
User ID: OFF

1. OK
2. Turn ON
```

3. Press 2 followed by Enter/On. A confirmation prompt is displayed, and the "Security" menu is displayed:

```
Security:  OFF

1. OK
2. Turn ON
```

Note: ***User ID****: must be* ***ON*** *to display the Security menu.*

4. Press 1 followed by Enter/On. The "Data Management" menu is displayed.

Disabling Optional Entry of User IDs:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 2 followed by Enter/On to display the current User ID setting:

```
User ID: ON

1. OK
2. Turn OFF
```

3. Press 1 followed by Enter/On. A confirmation prompt is displayed, and the "Security" menu is displayed:

```
Security:  ON

1. OK
2. Turn OFF
```

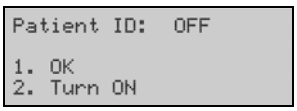
Note: ***User ID****: must be* ***ON*** *to display the Security menu.*

4. Press 2 followed by Enter/On. The "Data Management" menu is displayed.

Specifying Optional Entry of a Patient ID Whenever a Test is Run

Enabling Optional Entry of Patient IDs:

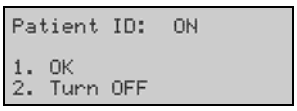
1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 3 followed by Enter/On to display the current Patient ID setting:



3. Press 2 followed by Enter/On. The "Data Management" menu is displayed.

Disabling Optional Entry of Patient IDs:

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 3 followed by Enter/On to display the current User ID setting:

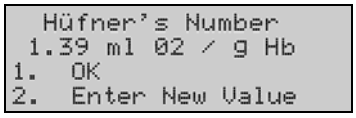


3. Press 2 followed by Enter/On. A confirmation prompt is displayed, and the "Data Management" menu is displayed.

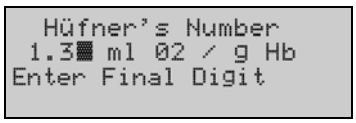
Specifying a Different Value for Hüfner's Number

Hüfner's number (the volume of oxygen that can be carried by one gram of hemoglobin) is used to calculate the oxygen content of a sample (see page 1). Although Hüfner's number is generally assumed to be 1.39 mL/gm, facilities may use a different value and may wish to set the ITC *AVOXimeter 4000* to match other instruments in the facility.

1. Display the "Calibration" menu (a submenu of Main Menu, see page 7).
2. Press 3 followed by Enter/On to display the screen for accepting or changing the value used for Hüfner's number:

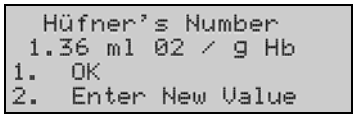


3. Press 2 followed by Enter/On to display the screen for entering a different value:



Note: *A default value of **1.39** is entered at the factory. Values ranging from **1.30** to **1.39** can be entered.*

4. Press the number key (e.g., 6) corresponding to the new value:



5. Check that the new Hüfner's number is correctly displayed, then press 1 followed by Enter/On. The "Calibration" menu is again displayed.
6. Press Cancel to return to the previous menu, if desired.

Calibration

The *ITC AVOXimeter 4000* is factory-calibrated and employs highly stable state-of-the-art light sources.

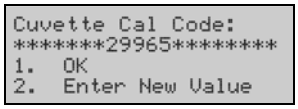
Cuvette Calibration Code

Accuracy of total hemoglobin measurements depends on using the correct cuvette calibration code (see page 1). The user must check the cuvette calibration code whenever using a different lot number of cuvettes.

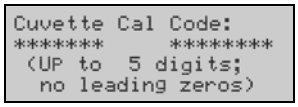
Note: *The lot number and calibration code are included on the carton label and bag for each lot of cuvettes.*

Entering a Different Cuvette Calibration Code:

1. Display the "Calibration" menu (a submenu of Main Menu, see page 7).
2. Press 1 followed by Enter/On to display the cuvette calibration code screen:



3. Press 2 followed by Enter/On to enter a new value. A screen for entering a new cuvette calibration code is displayed:



4. Enter the new calibration code, using the number keys, then press Enter/On. A confirmation screen is displayed.
5. Press 1 followed by Enter/On to confirm the new calibration code. The "Calibration" menu is again displayed.
6. Press Cancel to return to the previous menu, if desired.

Re-Calibration

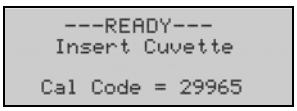
If the ITC *AVOXimeter 4000* results are out of range with either blood samples or controls and troubleshooting does not resolve the issue, re-calibration may be necessary. Please contact ITC Technical Support for more information on re-calibration.

4 Operation

Startup

If Entry of an Authorized User ID is Not Required: (see page 19)

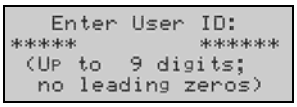
1. Press Enter/On. The instrument starts and performs a series of self-tests.
2. **"READY"** and "**Insert Cuvette"** are displayed when a test can be run:



3. Confirm that the Cal Code is the same as the one marked on the package of cuvettes. If not, change the Cal Code (see page 28).
4. Run the quality control test(s) for the day (see page 36).

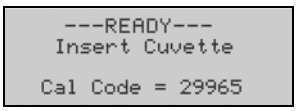
If Entry of an Authorized User ID is Required: (see page 19)

1. Press Enter/On. The instrument starts and performs a series of self-tests.
2. The screen for entering the User ID is displayed:



3. Enter the User ID, then press Enter/On. A confirmation screen is displayed:

4. Press 1 followed by Enter/On. **"READY"** and "**Insert Cuvette"** are displayed when a test can be run:



5. Confirm that the Cal Code is the same as the one marked on the package of cuvettes. If not, change the Cal Code (see page 28).
6. Run the quality control test(s) for the day (see page 36).

Sample Collection and Preparation

Sample Collection

Collect whole blood samples in a sodium or lithium heparinized syringe. Do not use samples that contain excessive volumes of anticoagulant or are diluted with saline.

Note: *Refer to CLSI document H18-A3, entitled "Procedures for the Handling and Processing of Blood Specimens – Approved Guideline, Third Edition" for additional information on sample collection.*

***CAUTION**: Universal safety precautions should be taken when handling and processing samples. Spills should be immediately disinfected with an appropriate disinfectant solution to avoid spreading contamination to laboratory personnel or equipment.*

Sample Preparation

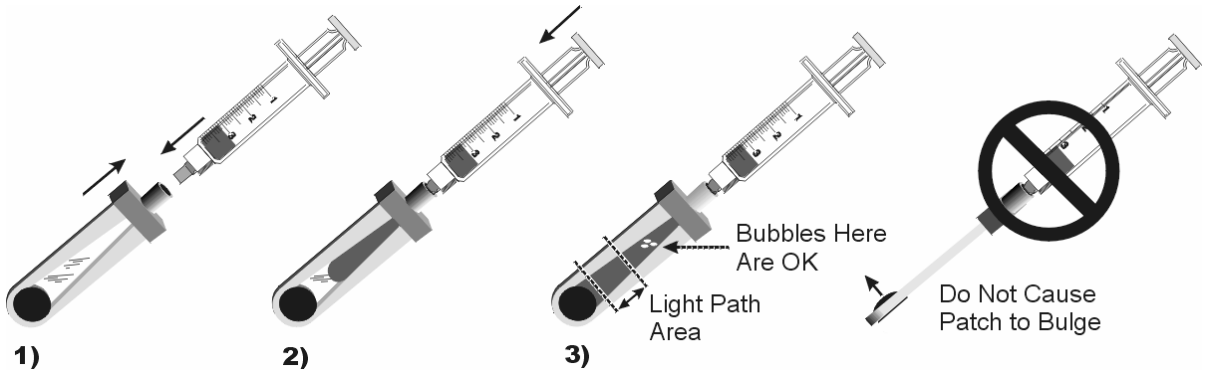
1. If the sample was not infused into the cuvette immediately after blood draw, mix the whole blood sample by rolling the syringe between the palms of your hands.
2. Connect a syringe containing the sample to an unused cuvette. Hold the cuvette by means of the finger grip on the black cap (see below).
3. Firmly holding the syringe and cuvette at a 45 degree angle, fill the cuvette by gently pressing the syringe plunger.

   ***CAUTION**: Never force sample into the cuvette. If a cuvette does not fill easily, discard it and use a new one.*

4. Stop filling the cuvette when the sample reaches the vent patch. Do not continue to fill the cuvette and cause the vent patch to bulge.

   ***CAUTION**: Carefully review the additional precautions on page 8.*

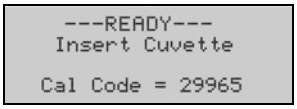
5. Verify that the light path area is free of bubbles.
6. Remove any blood from the exterior of the cuvette before placing the cuvette (with syringe still attached) into the test chamber.



Running a Test

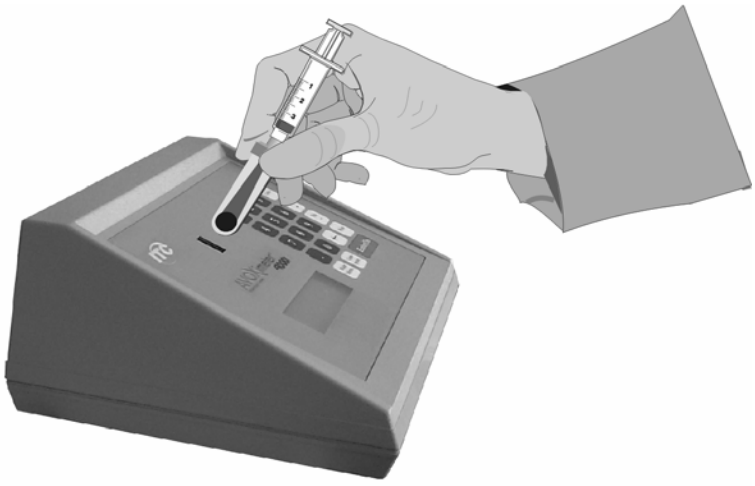
Running a Test on a Patient Sample

1. Verify that the instrument is ready to run a test and that the **"READY"** - "**Insert Cuvette"** screen is displayed:



2. Holding the cuvette by the finger grip on the black cap, insert the cuvette (with the syringe still attached) into the test chamber.

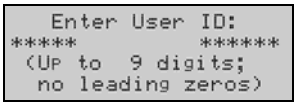
   Important: *Always keep the syringe attached when inserting the cuvette into the test chamber. Removing the syringe may cause inaccurate results.*



***CAUTION**: Never inject sample directly into the test chamber.*

***CAUTION**: Carefully review the additional precautions on page 8.*

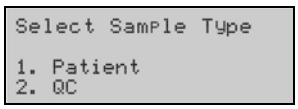
3. If optional entry of User IDs is enabled (see page 26), the screen for entering a User ID is displayed:



Enter the User ID, then press Enter/On. When the confirmation screen is displayed, press 1 followed by Enter/On.

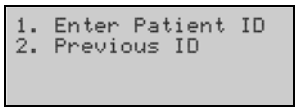
Note: To bypass entry of a User ID, either press Cancel, enter a zero and then press Enter/On, or simply press Enter/On when the screen for entering a User ID is displayed.

4. The screen for specifying the sample type is displayed:



5. Press 1 followed by Enter/On.

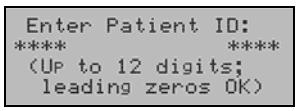
6. If optional entry of Patient IDs is enabled (see page 26), the screen for entering a Patient ID is displayed:



Note: To bypass entry of a Patient ID, press Cancel.

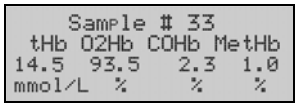
- If the Patient ID that was previously entered during the current session is to be used, press 2 followed by Enter/On. A confirmation screen is displayed.

- If a new Patient ID is to be entered, press 1 followed by Enter/On. The screen for entering a Patient ID is displayed:



Enter the Patient ID, then press Enter/On. When the confirmation screen is displayed, press 1 followed by Enter/On.

7. Test results are displayed within ten seconds:



Note: The oxygen content (O_2Ct) of the sample is calculated and included in the test record. The (O_2Ct) result is included in the results printout and in the stored data record, but is not displayed.

8. Holding the cuvette by the finger grip on the black cap, remove the cuvette from the test chamber.

Using the Printer

An optional printer can be connected by means of the serial port at the rear of the instrument (see page 9).

Note: *Contact your ITC representative to purchase the optional printer.*

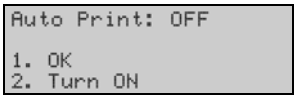
Printing the Current Test Results

1. When the test results are displayed on the screen, press [Print].

Specifying Automatic Printing of Results

The instrument can be configured so that results are automatically printed at the end of a test.

1. Display the "Printer Mode" menu (a submenu of [Main Menu], see page 7).
2. Press [1] followed by [Enter/On] to display the automatic printing screen:

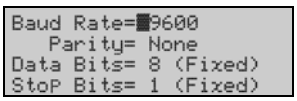


3. Press [2] followed by [Enter/On]. A confirmation prompt is displayed, and the "Printer Mode" menu is again displayed.
4. Press [Cancel] to return to the previous menu, if desired.

Changing the Serial Port Baud Rate and Parity

If a computer is being connected to the ITC *AVOXimeter 4000*, the baud rate and parity of the serial port on the instrument may need to be changed to optimize communication.

1. Display the "Printer Mode" menu (a submenu of [Main Menu], see page 7).
2. Press [3] followed by [Enter/On] to display the port parameters:



3. Press [Yes +] and/or [No --] to change the baud rate. When the correct value is displayed, press [Enter/On] to advance the cursor to the "Parity" field.
4. Press [Yes +] and/or [No --] to toggle between "NONE," "ODD," and "EVEN." When the correct value is displayed, press [Enter/On].
5. Press [Yes +] to confirm the new values. The "Printer Mode" menu is again displayed.
6. Press [Cancel] to return to the previous menu, if desired.

Data Management

Stored results can be reviewed, printed, and purged (if desired).

***CAUTION**: Once the instrument database contains the results of 100 tests, the results from the oldest test are automatically deleted when a test is run. Use the Data Transfer function to transfer data to an information system.*

Reviewing and/or Printing the Last Sample

1. (If needed) Turn on the printer.
2. Display the "Stored Data" menu (a submenu of Main Menu, see page 7).
3. Press 2 followed by Enter/On. The last test record is displayed:

```
    Sample # 33
 tHb O2Hb COHb MetHb
14.5  93.5   2.3  1.0
mmol/L  %     %    %
```

4. Press Enter/On again to display the second page of results for that sample.
   - The second and/or third page(s) of results for a Patient sample contains either the User ID, Patient ID, and calibration code, or if

```
S#33    USR231
Pt. ID: 985244

Cal Code: 29965
```

Note: *If* SO_2 is 'on' (see page 16), SO_2, O_2 content, and O_2 capacity will be shown on the second page of the patient record, and the User ID, Patient ID and calibration code will be shown on the third page.

```
    Sample # 32
  sO2   O2Ct   O2Cap
 94.1   18.5   19.0
   %    mL/dL  mL/dL
```

   - The second page of results for an optical quality control test contains the User ID and filter color:

```
S#18    USR231
Yellow OpticalFilter
```

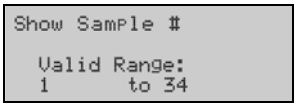
   - The second page of results for a liquid quality control test contains the User ID, liquid control lot number, cuvette lot number, and calibration code:

```
S#28    USR231
Level 1 Lot: 968544
Cuvette Lot: 332585
Cal Code: 29965
```

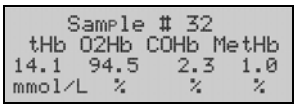
5. Press Print to print the test record.
6. Press Cancel to return to the previous menu, if desired.

Locating, Reviewing, and/or Printing any Sample

1. (If needed) Turn on the printer.
2. Display the "Stored Data" menu (a submenu of Main Menu, see page 7).
3. Press 1 followed by Enter/On. A screen to specify the test record number is displayed:



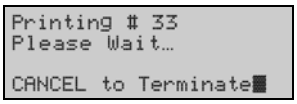
4. Enter the desired record number and press Enter/On to view the first page of the sample record:



5. Press Enter/On again to display the second and/or third page of results for that sample.
6. If needed, press Yes + (to view the next record) or No -- (to view the previous record).
7. Press Print to print a test record while it is displayed.
8. Press Cancel to return to the previous menu, if desired.

Printing all Stored Data

1. (If needed) Turn on the printer.
2. Display the "Printer Mode" menu (a submenu of Main Menu, see page 7).
3. Press 2 followed by Enter/On. All test records are printed, beginning with the latest test. The record number is displayed as each record is printed:



4. When printing is completed, the "Printer Mode" menu is again displayed.
5. Press Cancel to return to the previous menu, if desired.

Aborting Printing of Results

1. Press Cancel while results are printing to discontinue printing of additional results. A confirmation prompt is displayed, indicating that all samples were not printed.
2. Press Enter/On to return to the main menu.

Quality Control

Routine quality control testing should be part of a comprehensive quality assurance program. Quality control testing of the *ITC AVOXimeter 4000* consists of the following operations:

- Daily optical quality control.
- Weekly testing of one level of liquid controls.

In addition, the *ITC AVOXimeter 4000* performs a "self-check" to verify that the light source is operating properly every time it is turned on.

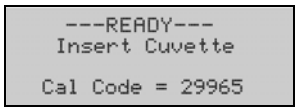
Note: *If quality control results are out of range, refer to the Troubleshooting section for instructions. If the "self-check" fails, contact ITC Technical Support (see page ii).*

Performing Optical Quality Control

The yellow and orange optical filters supplied with the *ITC AVOXimeter 4000* provide a convenient means of verifying that the optics are not obscured by blood or debris and that the instrument is properly calibrated. Each filter simulates a cuvette containing a blood sample of known composition and has a serial number that matches the serial number of the instrument.

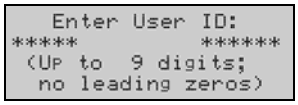
***CAUTION**: Each filter is labeled with a serial number that matches the serial number of the instrument. Verify that the serial number on each filter matches the serial number of the instrument when performing optical quality control. Each set of yellow and orange filters can only be used only with the ITC AVOXimeter 4000 of the same serial number and cannot be shared between different instruments.*

1. Verify that the instrument is ready to run a test and that the **"READY"** - "**Insert Cuvette"** screen is displayed:



2. Insert the yellow optical filter into the test chamber.

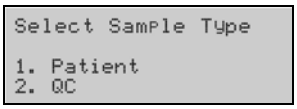
3. If optional entry of User IDs is enabled (see page 26), the screen for entering a User ID is displayed:



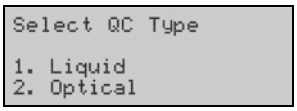
Enter the User ID, then press Enter/On. When the confirmation screen is displayed, press 1 followed by Enter/On.

Note: To bypass entry of a User ID, either press Cancel, enter a zero and then press Enter/On, or simply press Enter/On when the screen for entering a User ID is displayed.

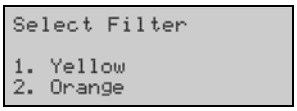
4. The screen for specifying the sample type is displayed:



5. Press **2** followed by Enter/On. The screen for specifying QC type is displayed:



6. Press **2** followed by Enter/On. The screen for specifying filter type is displayed:



7. Press the number key corresponding to the filter being run, followed by Enter/On. Press **1** followed by Enter/On to confirm your selection. A confirmation screen is displayed, and test results are displayed within ten seconds.

8. Record the THb, $\%O_2Hb$, %COHb, and %MetHb results, or print the results of the test (see page 35).

9. Press any key to clear the results, then repeat steps **2** through **8** using the orange filter.

10. Verify that the results for each filter are within the expected ranges listed below:

Optical Filter	Expected Range			
	tHb (g/dL)	**$\%O_2Hb$**	**%COHb**	**%MetHb**
Yellow	7.8 to 8.2	93.7 to 96.3	0.6 to 3.4	-0.4 to 2.4
Orange	16.7 to 17.3	37.8 to 40.2	20.0 to 23.0	0.2 to 1.8

Note: *The Expected Range is also shown on a sticker on the side of each filter.*

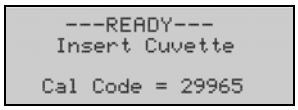
11. If desired, plot the optical filter results on daily logs such as the ones shown in the Quality Control Logs section on page 57.

Running Liquid Controls

ITC recommends either of the following Liquid Quality Controls (LQC):

- RNA CO-Oximeter controls, available from RNA Medical, Devens, MA., phone 978 772-9070 or toll-free 800-533-6162.
- Multi-4™ CO-Oximeter controls, available from Instrumentation Laboratory, Inc., Lexington, MA., phone toll-free 800-955-9525.

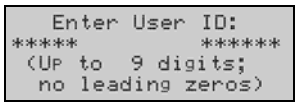
1. Verify that the instrument is ready to run a test and that the **"READY"** - "**Insert Cuvette"** screen is displayed:



2. Fill a test cuvette with a liquid control (see page 32).

3. Insert the test cuvette into the test chamber (see page 33).

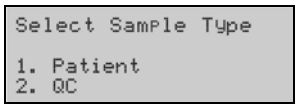
4. If optional entry of User IDs is enabled (see page 26), the screen for entering a User ID is displayed:



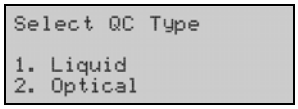
Enter the User ID, then press Enter/On. When the confirmation screen is displayed, press 1 followed by Enter/On.

Note: To bypass entry of a User ID, either press Cancel, enter a zero and then press Enter/On, or simply press Enter/On when the screen for entering a User ID is displayed.

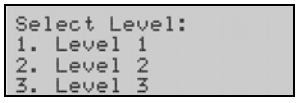
5. The screen for specifying the sample type is displayed:



6. Press 2 followed by Enter/On. The screen for specifying QC type is displayed:



7. Press 1 followed by Enter/On. The screen for specifying the control level is displayed:



8. Press the number key corresponding to the liquid control level being run, followed by Enter/On. A menu for selection of the liquid control lot number is displayed:

```
L2 Select Lot:
1. 943255
2. 122547
```

9. Select the previously entered (see page 38) lot number and press Enter/On. A cuvette lot number screen is displayed:

```
Cuvette Lot:
****** 725051*******
1.  OK
2.  Enter New Value
```

- If the previously entered cuvette lot number is to be used, press 1 followed by Enter/On. A confirmation screen is displayed.

- If a new lot number must be entered, press 2 followed by Enter/On. A screen for entry of the cuvette lot number is displayed:

```
Cuvette Lot:
******       *******
 (UP to  7 digits;
  no leading zeros)
```

Enter the new cuvette lot number, using the number keys, then press Enter/On. A confirmation screen is displayed.

10. Press 1 followed by Enter/On to confirm the cuvette lot number. A screen for final confirmation of the liquid control lot number and cuvette lot number is displayed:

```
Level 2 Lot: 943255
Cuvette Lot: 332585
1. OK
2. Re-enter
```

11. Press 1 followed by Enter/On to confirm the lot numbers. Test results are displayed within ten seconds.

12. Record the THb, $\%O_2Hb$, %COHb, and %MetHb results, or print the results of the test (see page 35).

13. Verify that the results are within the expected range of values for the liquid control.

14. If desired, plot the liquid control results on daily logs such as the ones shown in the Quality Control Logs section on page 57.

Entering Liquid Control Lot Numbers

Three lot numbers for each of three levels of liquid control can be entered into the instrument for later reference.

1. Display the "Data Management" menu (a submenu of Com-puter, see page 7).
2. Press 4 followed by Enter/On to display a menu for selection of a control level:

```
Select Level:
1. Level 1
2. Level 2
3. Level 3
```

3. Select the level for which a lot number is to be added and press Enter/On. A menu for selection of a lot number is displayed:

```
L2 Select Lot:
1. 943255
2. 122547
3. UNDEFINED
```

4. Select the lot to be changed and press Enter/On. A screen for entry of the lot number is displayed:

```
      QC Lot:
******        ******
1. OK
2. Enter New Value
```

5. Press 2 followed by Enter/On to enter a new value.
6. Enter the new lot number, using the number keys, then press Enter/On. A confirmation screen is displayed.
7. Press 1 followed by Enter/On to confirm the new lot number. The "Data Management" menu is again displayed.
8. Press Cancel to return to the previous menu, if desired.

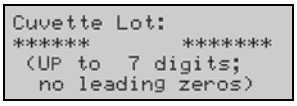
Entering Cuvette Lot Numbers

The lot number of cuvettes can be entered into the instrument for later reference.

1. Display the "Calibration" menu (a submenu of Main Menu, see page 7).

2. Press 2 followed by Enter/On to display the cuvette lot number screen:

3. Press 2 followed by Enter/On. A screen for entry of the cuvette lot number is displayed:



4. Enter the new cuvette lot number, using the number keys, then press Enter/On. A confirmation screen is displayed.

5. Enter the new lot number, using the number keys, then press Enter/On. A confirmation screen is displayed.

6. Press 1 followed by Enter/On to confirm the new lot number. The "Calibration" menu is again displayed.

Shutdown

1. Press Main Menu (see page 7).
2. Press 4 followed by Enter/On. The instrument will shut down.

Or:

1. Simultaneously press Main Menu and Cancel. The instrument will shut down.

Troubleshooting

Symptom	Possible Cause	Action Required
The instrument does not turn on.	1. The battery is discharged, and the AC Adapter is not connected to an AC outlet and/or the instrument.	1. Connect the AC Adapter to an AC outlet and the ITC *AVOXimeter 4000*.
The instrument does not respond to keystrokes or cuvette insertion.	1. The microprocessor is locked up.	1. Press the Main Menu and Cancel keys simultaneously to turn the instrument off, then turn the instrument back on. 2. If this fails, contact ITC Technical Support (see page ii).
Self-Test fails on power-up. The following error message is displayed: "**Cuvette Inserted???**"	1. A cuvette is inserted in the instrument. If a cuvette is not inserted in the instrument, see #2 below:	1. Remove cuvette, turn unit off and restart.
	2. Intensities are out of range.	2. At "**Cuvette Inserted???**" screen, press Enter/On twice for Diagnostic Mode. Press any key and then press Yes + to re-adjust light sources. When program finishes, turn the instrument off and then on.
	3. The cable from the detector to the circuit board is disconnected.	3. Open the case and check that the cables are properly connected.
	4. There is no power to the LEDs. The LED cable may be loose, disconnected or improperly placed on the connector at one or both ends.	4. Open the case and check that the cables are properly connected.
	5. One or more LEDs is defective.	5. Contact ITC Technical Support (see page ii).
	6. The cuvette door is partially open	6. Contact ITC Technical Support (see page ii).
The external printer is not printing.	1. There is no power to the printer.	1. Connect the printer to an AC outlet and turn on the printer.
	2. The printer is not connected to the instrument.	2. Connect the printer to the ITC AVOXimeter 4000 (see page 9).
	3. The wrong print mode, baud rate, or parity is selected.	3. Specify the proper values for the printer (see page 35).
	4. The microprocessor is locked up.	4. See above.

Symptom	Possible Cause	Action Required
Measurements of $\%HbO_2$ are not accurate	1. The optical detector may be contaminated by blood or foreign material.	1. Run optical quality control. If needed, clean the optical detector (see page 49).
	2. The instrument may require calibration.	2. Re-calibrate the instrument (see page 29).
Measurements of THb are not accurate	1. The wrong cuvette calibration code is entered into the instrument.	1. Obtain the correct cuvette calibration code from the cuvette carton and enter the value (see page 29).
	2. The optical detector may be contaminated by blood or foreign material.	2. Clean the optical detector (see page 49).
	3. The instrument may require calibration.	3. Re-calibrate the instrument (see page 29).
One of the following ERROR: messages is displayed: **"%HbO2<> XX.X%"** or **"%HbCO<> XX.X%"** or **"%HbMet<> XX.X%"** or **"%RHb<> XX.X%"**	1. A cuvette without a sample was inserted.	1. Test a new cuvette that contains the sample.
	2. The cuvette was not properly filled.	2. Ensure that the sample reaches the vent patch when filling and that there are no air bubbles in the optical window.
	3. The optical detector may be contaminated by blood or foreign material.	3. Run optical quality control. If needed, clean the optical detector (see page 49).
	4. LED intensities are too low.	4. Remove cuvette, turn unit off, and restart. Verify that the self test passes.
	5. The sample is lipemic.	5. If possible, obtain a replacement sample that is not lipemic.
The following ERROR: message is displayed: **"THb < 4.0 g/dL"**	1. THb may actually be low. In this case, values of THb and $\%HbO_2$ not likely to be accurate.	1. Contact ITC Technical Support (see page ii).
The following ERROR: message is displayed: **"THb > 25.0 g/dL"**	1. THb may actually be high. In this case, values of THb and $\%HbO_2$ not likely to be accurate.	1. Contact ITC Technical Support (see page ii).
THb and/or %HbO2 readings for yellow or orange filter are out of range.	1. The optical detector may be contaminated by blood or foreign material.	1. Clean the optical detector (see page 49).
	2. The instrument may require calibration.	2. Re-calibrate the instrument (see page 29).

Symptom	Possible Cause	Action Required
The following ERROR: message is displayed: **"Uninitialized Vector Service Required"**	1. Microprocessor error.	1. Press the Main Menu and Cancel keys simultaneously to turn the instrument off, then turn the instrument back on. 2. If the problem persists, contact ITC Technical Support (see page ii).

5 Maintenance

Periodic maintenance procedures must be performed on the ITC *AVOXimeter 4000* in order to assure consistent efficient performance or to repair/replace user-serviceable components.

Inspect and clean the exterior of the instrument as required. Remove residual dried blood or other foreign matter using a water-dampened cloth.

Only qualified personnel should perform maintenance as described in this manual.

***CAUTION**: Maintenance procedures involving opening the instrument are only to be conducted after assuring that the AC adapter has been disconnected from both the instrument and a source of AC power.*

All maintenance procedures performed on the instrument should be documented in order to comply with requirements for laboratory quality assurance.

Verification of Instrument Temperature

Materials Needed:

1. A thermometer that is calibrated and traceable to National Institute of Standards and Technology (NIST) standards (or other national standards). The thermometer should be accurate to ±0.5 °C
2. Rubber bands or adhesive tape

1. Using rubber bands or adhesive tape, attach the bulb end of the thermometer to the circular disk at the end of the *ITC AVOXimeter 4000* temperature probe.

2. Ensure that the probe and the thermometer are in a thermally stable environment and not in air currents.

3. Start the instrument.

4. Wait ten minutes.

5. Display the battery status screen (page 14).

6. Record the temperatures displayed on the battery status screen. Then read the thermometer and record it as well.

7. If the *ITC AVOXimeter 4000* temperature reading is within ± 3°C of the NIST traceable thermometer, the *ITC AVOXimeter 4000* is properly calibrated. If the *ITC AVOXimeter 4000* differs from the thermometer by more than 3°C, call ITC Technical Support (800) 631-5945.

Cleaning the Optical Detector

Materials Needed:
1. # 0 Phillips screwdriver
2. 5 mm nutdriver
3. 1/4 inch nutdriver

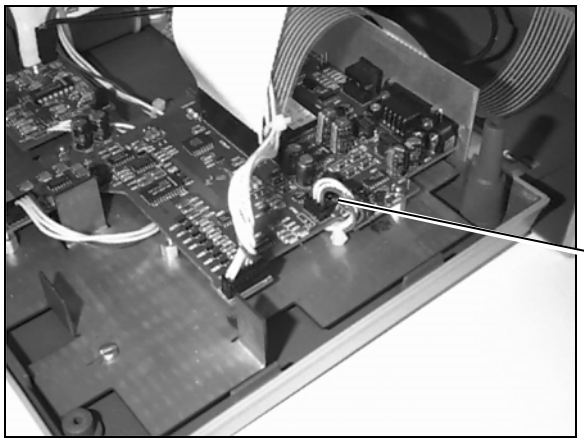
1. Disconnect the ITC *AVOXimeter 4000* from the AC Adapter.

2. Remove the four screws from the bottom of the instrument, using the #0 Phillips screwdriver.

3. Holding the upper and lower covers together, place the instrument in the upright position, with the keypad to your right.

4. Slowly and carefully lift the upper cover, keeping it parallel with the lower part of the instrument, until the upper cover is free of the rear panel.

5. Locate the cable that runs from the battery pack to the main circuit board (see below). Disconnect the cable from the **J302** connector on the main circuit board.

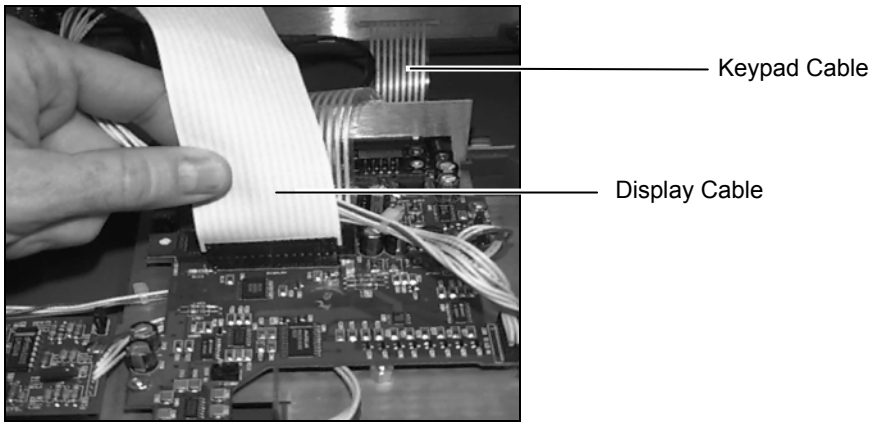


6. Tilt the upper cover backward to fully expose the main circuit board and small circuit board on the lower part of the instrument.

7. Locate the flat keypad cable that runs from the keypad to the main circuit board. Disconnect the cable from the **Keyboard** (**J101**) connector on the main circuit board.

8. Locate the flat LCD cable that runs from the LCD to the main circuit board. Disconnect the cable from the **Display** (**J102**) connector on the main circuit board.

Note: Grasp only the connector at the end of the cable. Gently rock the connector in an upward direction to remove it.

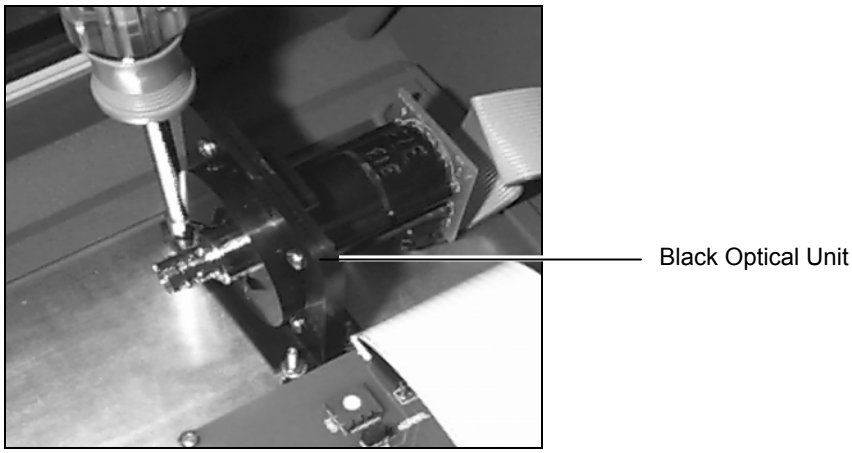


9. Locate the flat cable that runs from the black optical unit to the main circuit board. Disconnect the cable from the **J203** connector on the main circuit board.

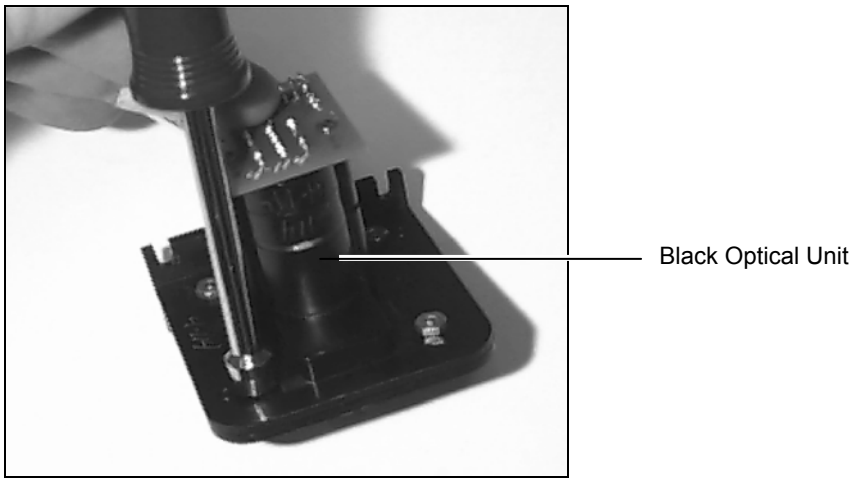
10. Locate the coaxial cable that runs from the black optical unit to the small circuit board. Disconnect the cable from the **J1XX** connector on the small circuit board.

11. The upper cover containing the black optical unit can now be rested on a table with the front panel facing down.

12. Using the 5mm nutdriver, remove the four nuts (and washers, if applicable) that secure the black optical unit to the front panel. Then remove the black optical unit from the instrument.

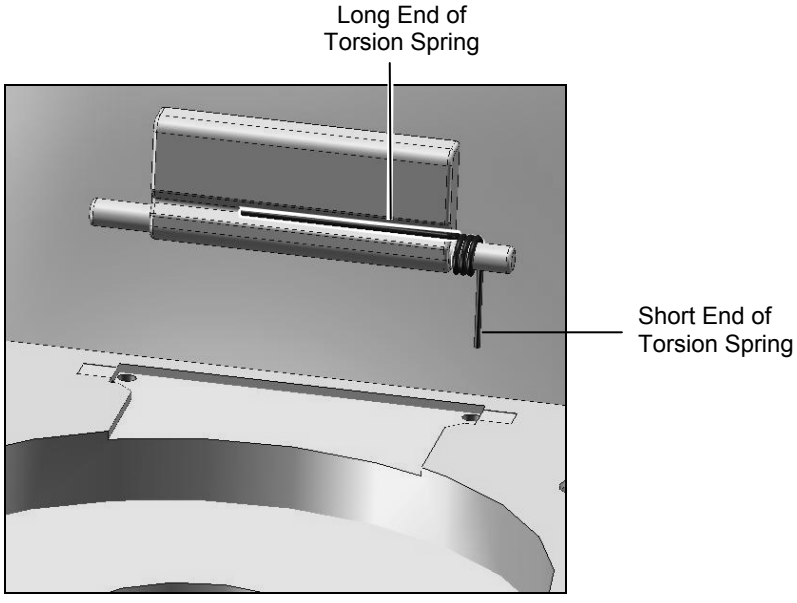


13. Using the 1/4" nutdriver, remove the four screws and four nuts that secure the two halves of the black optical unit. Take care when separating the two halves of the optical unit. Do not lose the small torsion spring or the shutter door. Set them aside in a safe place for reassembly.

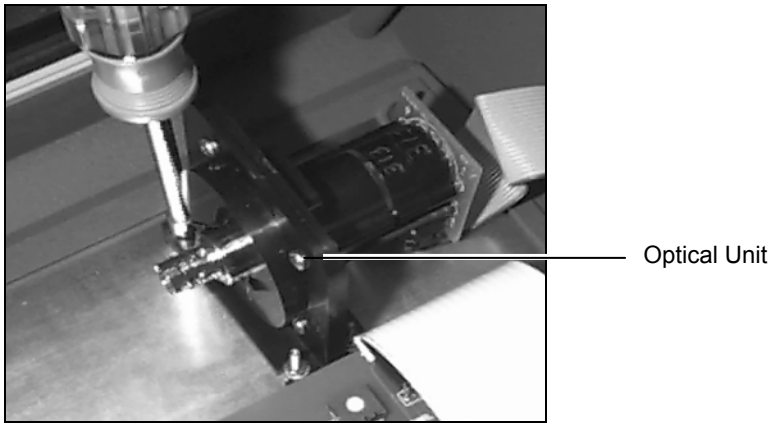


14. Clean the exposed detector with gauze pads dampened with detergent. Do not use abrasives. Then dry off the detector surface, making sure that it is clean. Remove any other debris inside the optical unit.

15. Reassemble the two halves of the optical unit, making sure that the shutter door and torsion spring are installed correctly (the two door ribs will face outward). **One leg of the spring fits into a hole in the door slot, the other leg rests behind the shutter door.** Bolt the optical unit back together.



16. Place the optical unit back on the front panel. Using the 5mm nutdriver, secure the black optical unit to the front panel with the four nuts (and washers, if applicable).



17. Position the upper cover (containing the black optical unit) in an upright position over the lower part of the instrument, with the keypad to the right.

18. Connect the coaxial cable from the optical unit to the **J1XX** connector on the small circuit board.

19. Connect the flat cable from the optical unit to the **J203** connector on the main circuit board.

20. Connect the flat cable from the LCD to the **Display** (**J102**) connector on the main circuit board.

21. Connect the flat cable from the keypad to the **Keyboard** (**J101**) connector on the main circuit board.

22. Connect the cable from the battery pack to the **J302** connector on the main circuit board.

23. Slowly and carefully lower the upper cover onto the lower part of the instrument, ensuring that the metal rear panel slides into the center slot at the rear of the upper cover.

Note: *Ensure that the cables are not snagged or crimped between components when lowering the upper cover onto the lower part of the instrument.*

24. Using the #0 Phillips screwdriver, secure the bottom of the instrument to the upper cover with the four screws.

25. Connect the AC adapter and turn on the instrument. The self-test should run and the "**Ready – Insert Cuvette**" screen should be displayed.

Note: *If the self-test fails or an error message is displayed, the most likely cause is improper reassembly or incorrect connections. Should this occur, disconnect the AC adapter and confirm that all connections have been made properly. Should the problem persist, contact ITC Technical Support.*

26. Reset the time and date (see page 16), and run optical quality control (see page 36)

Replacing the Battery

Materials Needed:
1. # 0 Phillips screwdriver
2. Diagonal cutting pliers
3. Replacement battery with cable (E4-BATP)
4. Securing cording (packaged with replacement battery)

1. Steps 1 through 11 of the *Verification of Instrument Temperature*

Materials Needed:
1. A thermometer that is calibrated and traceable to National Institute of Standards and Technology (NIST) standards (or other national standards). The thermometer should be accurate to ±0.5 °C
2. Rubber bands or adhesive tape

2. Using rubber bands or adhesive tape, attach the bulb end of the thermometer to the circular disk at the end of the *ITC AVOXimeter 4000* temperature probe.

3. Ensure that the probe and the thermometer are in a thermally stable environment and not in air currents.

4. Start the instrument.

5. Wait ten minutes.

6. Display the battery status screen (page 14).

7. Record the temperatures displayed on the battery status screen. Then read the thermometer and record it as well.

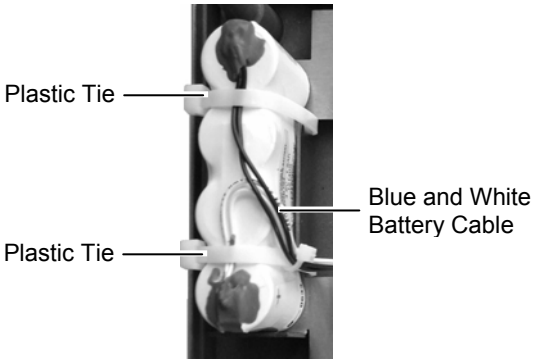
8. If the *ITC AVOXimeter 4000* temperature reading is within ± 3°C of the NIST traceable thermometer, the *ITC AVOXimeter 4000* is properly calibrated. If the *ITC AVOXimeter 4000* differs from the thermometer by more than 3°C, call ITC Technical Support (800) 631-5945.

9. Cleaning the Optical Detector **procedure on page 49 Must be performed before moving to step 2 of "Replacing the Battery", below.**

Note: *The battery is housed in the lower cover.*

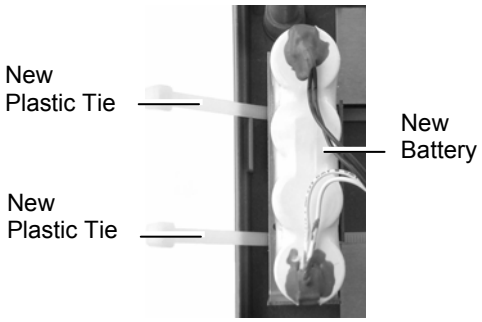
10. Using the diagonal cutting pliers, cut the plastic ties that secure the battery to the frame.

Note: *Be sure to cut only the white plastic ties that are wrapped around the battery and secure it to the lower cover. Do not cut the blue and white power cables that are connected to the top of the battery.*



11. Remove the battery, being careful not to snag any components when pulling the cable out from underneath the main circuit board. If the battery well contains tape, remove the tape.

12. Remove the liner from the tape on the bottom of the new battery, and place the new battery in the battery well with the tape side down, ensuring that the blue and white cables are facing up, then route the new plastic ties (packaged with the replacement battery) underneath the battery well.



13. Secure the new battery in the battery well, using the new white plastic ties.

Note: *When securing the battery to the battery well, be sure that the plastic ties are routed underneath the battery well. Cut the excess length from the plastic ties using the diagonal cutting pliers.*

14. Thread the blue and white battery cable of the new battery under the main circuit board.

15. Re-connect the cables, replace the upper cover of the ITC AVOXimeter, connect the AC adapter, and turn on the instrument.as outlined in Steps **17** through **25** of the *Cleaning the Optical Detector* procedure on page 49. The self-test should run and the "**Ready – Insert Cuvette**" screen should be displayed.

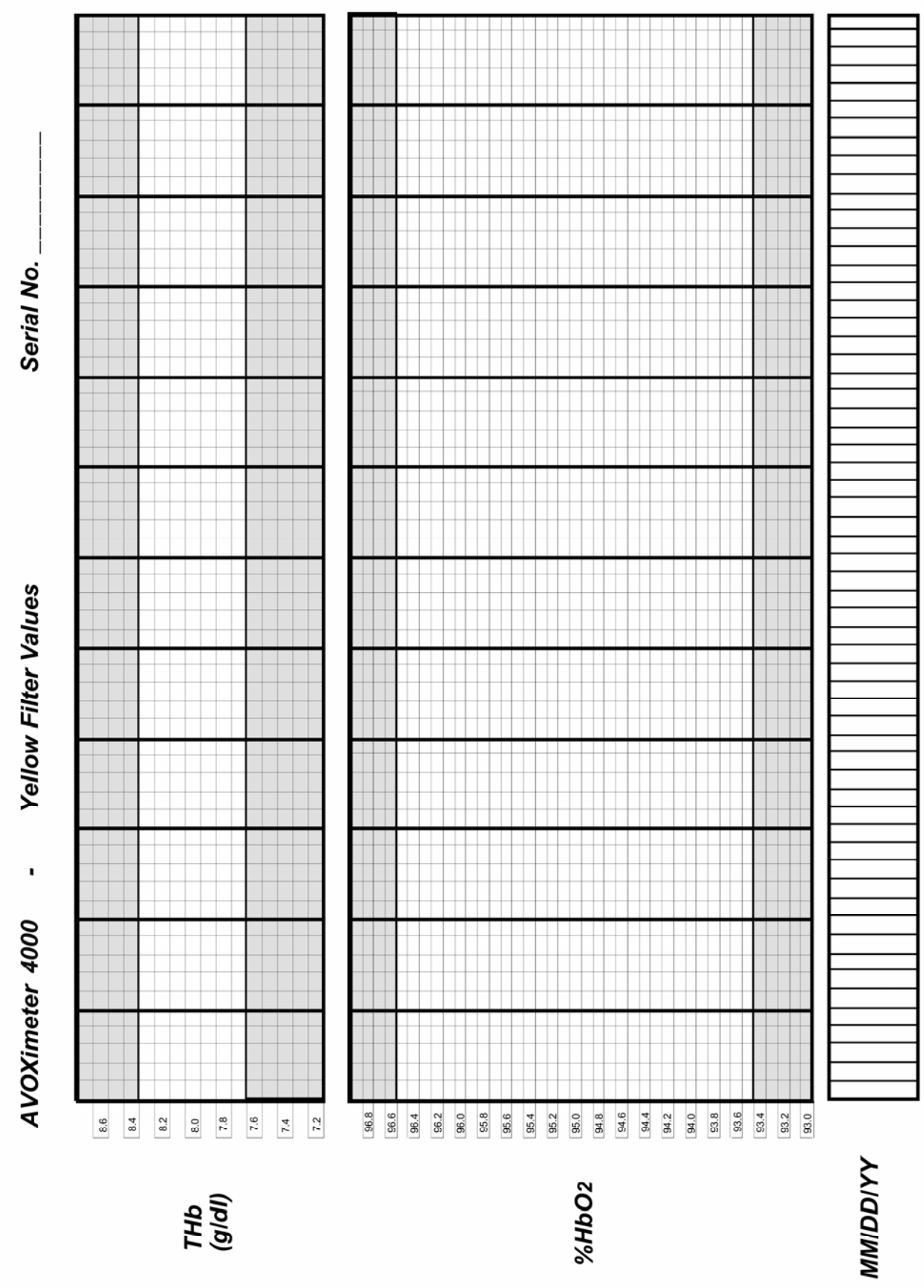
Note: *Be sure to connect the blue and white battery cable last.*

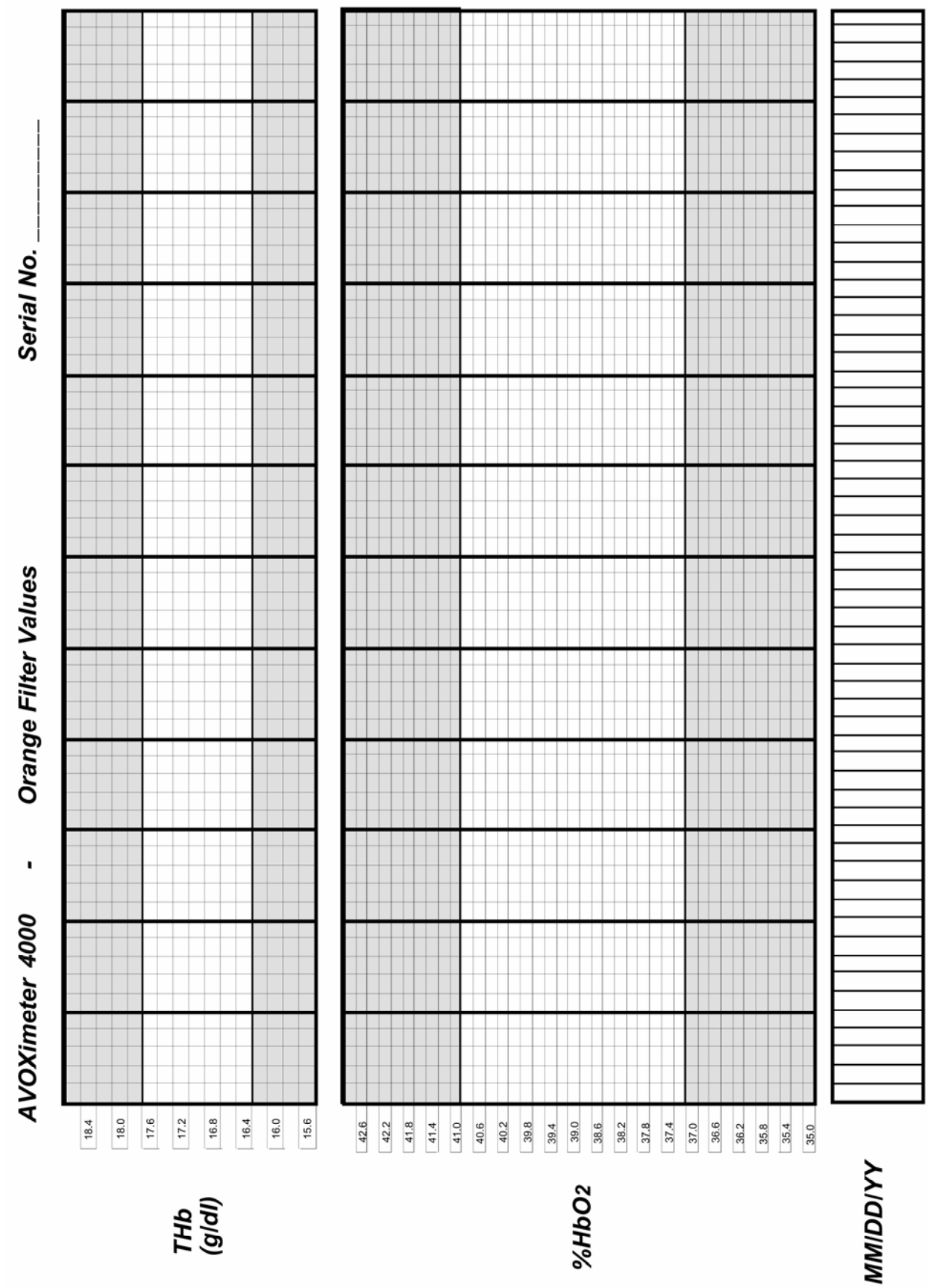
The new battery is not charged. To ensure adequate charge, leave the instrument connected to the AC Adapter for a minimum of eight hours. Tests can be run while the instrument is charging.

16. Reset the time and date (see page 16).

6 Quality Control Logs

Quality control logs for the yellow and orange filters are shown on the following pages.


AVOXimeter 4000 - Yellow Filter Values
Serial No. _____
THb (g/dl)
8.6
8.4
8.2
8.0
7.8
7.6
7.4
7.2
%HbO2
96.8
96.6
96.4
96.2
96.0
95.8
95.6
95.4
95.2
95.0
94.8
94.6
94.4
94.2
94.0
93.8
93.6
93.4
93.2
93.0
MM/DD/YY


AVOXimeter 4000 - Orange Filter Values
Serial No. _____
THb (g/dl)
18.4
18.0
17.6
17.2
16.8
16.4
16.0
15.6
%HbO2
42.6
42.2
41.8
41.4
41.0
40.6
40.2
39.8
39.4
39.0
38.6
38.2
37.8
37.4
37.0
36.6
36.2
35.8
35.4
35.0
MM/DD/YY

7 Warranty

Certification, Warranty and Service Warranty, and Service

ITC, declares to the original purchaser that each instrument manufactured and sold by ITC, or sold by an authorized ITC dealer, shall be free from defects in material and workmanship and, under normal and proper use conditions, warrants it for a period of one year from installation and no more than 13 months from the shipping date, except as otherwise provided in writing.

ITC's obligation is limited to repairing, replacing, or modifying (at ITC's undisputed judgment) at ITC's factory, or elsewhere, the material whose defects have been verified, on condition that the purchaser has informed ITC of any defects found within 15 days from receipt. Damages caused by or connected to transport are excluded. Transport to and from ITC facility will be at purchaser's charge and risk, and shall also be prepaid for reshipment, except as otherwise provided in writing. These replacements, repairs, or alterations will in no case determine extension to the above specified warranty period.

The warranty does not cover those parts that deteriorate, or which are in any case considered consumables, or those parts or "items", which by their nature are normally required to be replaced periodically consistent with normal maintenance. It is also understood that, following the purchase and delivery of the instrument, the purchaser shall be deemed liable for any losses, damages, or complaints concerning persons or things incurred by the use, or misuse of the instrument, on behalf of the purchaser, its employees, co-operators, or others. ITC does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements, as well as for any damage to the instrument, directly or indirectly resulting from the use of reagents and/or consumables different from those produced by ITC specifically for its own instruments, and for the same properly tested.

Warranty will not apply to those defective instruments or materials showing defects or damage arising from the following causes:

1. Insufficient or negligent care by the purchaser.

2. Insufficient or negligent maintenance by the purchaser in relation to the instructions contained in the manuals prepared by ITC for this purpose; tampering or alterations of the instruments, or in any case interventions or repairs made by any person not duly authorized by ITC.

3. Misuse due to carelessness, negligence, or inexperience.

4. Employment of materials under heavier conditions than those for which they have been designed and manufactured, and use of the same in combination with incompatible or dangerous products.

5. Non-observance of the regulations relevant to installation, power supply, and operation of the instruments (with particular regard to the regulations for accident prevention).

THIS WARRANTY IS GIVEN EXPRESSLY AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. PURCHASER AGREES THAT THERE IS NO WARRANTY OR MERCHANTABILITY AND THAT THERE ARE NO OTHER REMEDIES OR WARRANTIES, EXPRESS OR IMPLIED, WHICH EXTEND BEYOND THE CONTENTS OF THIS AGREEMENT.

No agent or employee of ITC is authorized to extend any other warranty or to assume for ITC any liability except as above set forth.

Please contact ITC Technical Support if any malfunction is discovered.

8 Safety Standards

The ITC *AVOXimeter* 4000 instrument complies with the following safety standard requirements and directives:

CSA C22.2. 601.1.	Medical Electrical Equipment –General Requirements for Safety
EN 60601-1/ UL/IEC 60601-1	Medical Electrical Equipment – General Requirements for Safety
EN 60601-1-2 / IEC 60601-1-2	Medical Electrical Equipment – Part 1-2 – General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

Directives: 89/336/EEC and as amended by 91/263/EEC, 92/31/EEC, 93/68/EEC and 98/13/EC, 98/79/EC

Equipment Classifications As Defined Per UL 60601-1:2003/ IEC60601-1 2nd Edition

Protection against electrical shock: Class II, Internally Powered Equipment with no applied parts

Protection against ingress of liquids: Ordinary (no protection as defined by IEC 529)

Product cleaning and disinfection: Only according to recommendations of the manufacturer's accompanying documentation

Mode of operation of equipment: Continuous

Degree of safety of application in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide: Not Suitable

Note: *As defined in the above standards, the classification of "Not Suitable" DOES NOT MEAN that the instrument is not suitable for use in an Operating Room (OR) environment. Rather, it is intended to indicate that the instrument is not suitable for use in the direct presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.*

All relevant documentation is kept on file at ITC.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The ITC *AVOXimeter* 4000 is intended for use in the electromagnetic environment specified below. The customer or the user of the *ITC AVOXimeter 4000* should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ITC AVOXimeter 4000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ITC AVOXimeter 4000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The ITC *AVOXimeter 4000* is intended for use in the electromagnetic environment specified below. The customer or the user of the ITC *AVOXimeter 4000* should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T for 0.5 cycle) 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T for 0.5 cycle) 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the ITC AVOXimeter 4000 System requires continued operations during power mains interruptions, it is recommended that the ITC AVOXimeter 4000 System be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

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International Technidyne Corporation
8 Olsen Avenue • Edison, NJ 08820 USA
tel: 732.548.5700 • fax: 732.248.1928
www.itcmed.com
a subsidiary of Thoratec Corporation

EC REP
MDSS
Burckhardtstrasse 1
30163 Hannover
Germany

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